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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/740,698	12/19/2003	Sign Erickson Varner	56086 (71699)	3885

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EXAMINER	
HUH, BENJAMIN	
ART UNIT	**PAPER NUMBER**
3767	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/14/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/740,698	VARNER ET AL.	
	Examiner	Art Unit	
	Benjamin Huh	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *68-129* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *68-129* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/11/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 68-91, 111-116, 121-127, & 129 are rejected under 35 U.S.C. 102(e) as being anticipated by Rosenman et al (US Patent No. 6478776 B1). The Rosenman et al reference discloses in figures 8-19 an implantable drug delivery device 12 comprising a non-linear shaped body member having at least two deviations from a linear path and that has a shape other than a substantially C-configuration and that is implanted within a patient to deliver a drug substance to the patient via the body member; and a cap element 56 that abuts an incision, seen as abutting the incision from within the tissue, through which the device is inserted to stabilize the device once implanted, wherein the cap is seen to stabilize the device through the fact that it will help anchor the device, also wherein the cap is seen to be fully capable of mating against an eye due to it's size, shape, and ability to work in the environment, see abstract , figures cited above, and col. 5 lines 40 – col. 12 line 23.

With respect to claims 69-73, see figures 8-19.

With respect to claims 74-75, wherein the cap element 56 that is fully capable of mating against a patient eye outer surface while the body member is inserted into the eye due to it's size, shape, and ability to work in the environment, see figures 18-19.

With respect to claims 76, wherein the device comprises a therapeutic agent for delivery to the patient during use of the device, see col. 3 line 67 – col. 4 line 32, col. 5 line 40 – col. 6 line 10, col. 15 line 9 – col. 16 line 35, & abstract.

With respect to claims 77-78, wherein the body member comprises a polymer and comprises a therapeutic substance that can be delivered to the patient eye, see col. 10 lines 21-36 & col. 15 line 9 – col. 16 line 35.

With respect to claims 79-82, the reference disclosing an implantable drug delivery device comprising a coil-shaped body member 12 that is fully capable of being implanted within an eye during use of the device to deliver a drug substance to the patient via the body member due to it's size, shape and ability to work in the environment, also see abstract, figures 4-5 & 8-19, and col. 5 lines 40 – col. 12 line 23

With respect to claims 83-88, the reference also discloses the method for treating a patient comprising providing a delivery device comprising a helical, substantially Z-shaped, body member 12 having at least five deviations from a linear path and that has a shape other than a substantially C-configuration; and inserting into a patient the device whereby the body member resides in the patient and a therapeutic substance is administered to the patient via the body member, wherein the device is inserted through an incision created by the device, and wherein the cap element 56 abuts the incision

from within the tissue and is fully capable of stabilizing the device due to it's size and shape, wherein the extra element inherently adds to the stability of the device, see abstract, col. 3 line 67 – col. 4 line 32, col. 5 lines 40 – col. 12 line 23, figures 4-5 & 8-19.

With respect to claim 89, see col. 16 lines 15-35.

With respect to claim 90-91, wherein the body member comprises a polymer and comprises a therapeutic substance that can be delivered to the patient eye, see col. 10 lines 21-36 & col. 15 line 9 – col. 16 line 35.

Claims 93-97, 99-107, 109, 118, 120-121, 126-127, & 129 are rejected under 35 U.S.C. 102(b) as being anticipated by Darougar et al (US Patent No. 5395618). The Darougar et al reference discloses the device and method of insertion of an ocular insert in figures 7-12 disclosing a drug delivery device comprising a non-linear shaped body member having at least two deviations from a linear path and inserting the device into a patient eye for administering a substance to a patient, wherein the device can be helical shaped or have multiple deviations from a linear path, wherein protrusions/deviations 76 or 86 or 92 or 102 or 112 or 113 are all seen to be deviations off of a linear path.

Claims 68-91, 111-116, 121-127, & 129 are rejected under 35 U.S.C. 102(b) as being anticipated by Altman (US Patent No. 5551427). The Altman reference discloses in figures 7-11 an implantable drug delivery device comprising a non-linear shaped body

member 46 having at least two deviations from a linear path and that has a shape other than a substantially C-configuration and that is implanted within a patient to deliver a drug substance to the patient via the body member; and a cap element 54 that abuts an incision, seen as abutting the incision from within the tissue, through which the device is inserted to stabilize the device once implanted, wherein the cap is seen to stabilize the device through the fact that it will help anchor the device, also wherein the cap is seen to be fully capable of mating against an eye due to it's size, shape, and ability to work in the environment, see abstract , figures cited above, and col. 9 line 52 – col. 11 line 67.

Claims 68-71, 74-78, 83-86, 90-92, 99-102, 104, 106-110, 116-121& 128-129 rejected under 35 U.S.C. 102(b) as being anticipated by Richter et al (US Patent No. 5868697). The Richter reference discloses in figures 1, 9, 11, & 13 an implantable drug delivery device comprising a non-linear shaped body member (30,130) having at least two deviations from a linear path and that has a shape other than a substantially C-configuration and that is implanted within a patient to deliver a drug substance to the patient via the body member, see col. ; and a cap element (34,134) that abuts an incision, seen as abutting the incision from within the tissue, through which the device is inserted to stabilize the device once implanted, wherein the cap is seen to stabilize the device through the fact that it will help anchor the device, also wherein the cap is seen to be fully capable of mating against an eye due to it's size, shape, and ability to work in the environment, see abstract , figures cited above, and col. 7 lines 51-53, col. 7 line 57 – col. 8 line 47.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 92 is rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenman et al (US Patent No. 6478776 B1) in view of Johnson (US Patent No. 5972027). Now even though Rosenman does not explicitly disclose the device comprising a shape memory material attention is directed to Johnson. The Johnson reference teaches an implantable drug delivery device with a non-linear shaped body member that can be made of nitinol, a very well known shape memory alloy of nickel-titanium, see col. 2 lines 39-56. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device and use of Rosenman to utilize the teachings of Johnson to comprise the device of a shape memory material in order to provide a bio-compatible and strong device.

Claim 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over Darougar et al (US Patent No. 5395618) in view of Johnson (US Patent No. 5972027). Now even though Darougar et al does not explicitly disclose the device comprising a shape memory material attention is directed to Johnson. The Johnson reference teaches an implantable drug delivery device with a non-linear shaped body member that

can be made of nitinol, a very well known shape memory alloy of nickel-titanium, see col. 2 lines 39-56. Therefore, it would be obvious to one of ordinary skill in the art at the time of the invention to modify the device and use of Darougar et al to utilize the teachings of Johnson to comprise the device of a shape memory material in order to provide a bio-compatible and strong device.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. The applicant is directed to the rejections above with respect to the amendments and comments.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Benjamin Huh whose telephone number is 571-272-8208. The examiner can normally be reached on M-F: 9:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BHH

BHH

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons